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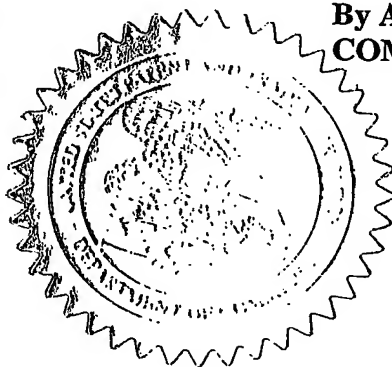
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# PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

## CERTIFICATE OF MAILING BY "EXPRESS MAIL"

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Lisa Amii

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☐ Additional inventors are being named on the \_\_\_ separately numbered sheets attached hereto.

## TITLE OF THE INVENTION (280 characters max)

IMPLANT DELIVERY DEVICE

## CORRESPONDENCE ADDRESS

Direct all correspondence to:

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PATENT TRADEMARK OFFICE

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## ENCLOSED APPLICATION PARTS (check all that apply)

☒ Specification Number of Pages 29  
☒ Drawing(s) Number of Sheets 13  
☒ Application Data Sheet, See 37 CFR 1.76 - 2 pages

☐ CD(s), Number  
☒ Other (specify) Return Postcard

## METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☒ Applicant claims small entity status. See 37 CFR 1.27.  
☐ A check or money order is enclosed to cover the filing fees.  
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\$80.00

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.  
☒ No.  
☐ Yes, the name of the U.S. Government agency and the Government contract number are: \_\_\_\_\_

Respectfully submitted,

SIGNATURE

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Date: March 26, 2003

REGISTRATION NO. 48,199  
(if appropriate)

Docket Number: 544103000100

## USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

pa-776773

## **Application Data Sheet**

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### **Application Information**

Title Line One:	IMPLANT DELIVERY DEVICE
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Formal Drawings?:	No
Application Type:	Provisional
Docket Number:	544103000100

### **Representative Information**

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### **Continuity Information**

This application is a:  
> Application One:

Filing Date:

which is a:

>>Application Two:

Filing Date:

which is a:

>>>Application Three:

Filing Date:

**Prior Foreign Applications**

Foreign Application One:

Filing Date:

Country:

Priority Claimed:

## IMPLANT DELIVERY DEVICE

### FIELD OF THE INVENTION

[0001] This invention relates to devices and methods for placing one or more implants such as helical scaffolds or occlusive members into tubular organs or open regions of the body. The implants may be of types that maintain patency of an open anatomical structure, occlude a selected volume, isolate a region, or collect other occlusive members at a site. Included in the description are devices and methods for deploying the various implants, typically without a sheath, in a serial fashion, and with high adjustability.

### BACKGROUND OF THE INVENTION

[0002] Implants such as stents and occlusive coils have been used in patients for a wide variety of reasons. For instance, stents are often used to treat arterial stenosis secondary to atherosclerosis. Various stent designs have been developed and used clinically, but self-expandable and balloon-expandable stent systems and their related deployment techniques are now predominant. Examples of self-expandable stents currently in use are WALLSTENT® stents (Schneider Peripheral Division, Minneapolis, MN) and Gianturco stents (Cook, Inc., Bloomington, IN). The most commonly used balloon-expandable stent is the PALMAZ® stent (Cordis Corporation, Warren, NJ).

[0003] Typically, after balloon angioplasty has been performed, either a self-expandable or balloon-expandable stent is advanced over a guidewire and positioned at the target site. A protective sheath or membrane is then retracted proximally to allow expansion of a self-expanding stent. Alternatively, a delivery balloon may be inflated, thereby expanding the stent.

[0004] Despite improvements in delivery systems, balloon design, and stent design, these over-the-guidewire and/or sheathed self-expanding stent deployment

systems still have their limitations. For instance, sheathed stents tend to move forward when the sheath is pulled back, deploying them imprecisely. The sheathed design also requires that the stent delivery system be larger in diameter and less flexible. Furthermore, for sheathed systems, the interventional procedure may only proceed if the vessel of interest is of sufficiently large diameter to allow sheath placement to avoid significant damage to the luminal surface of the vessel.

Moreover, balloon-expandable stents, by virtue of a large diameter and relative inflexibility, are often unable to reach distal vasculature. For both self-expandable and balloon-expandable stent deployment systems, repositioning or step-wise release of the stent are usually not available features. Similarly, occlusive coil placement systems such as systems that deliver detachable platinum coils and GDC® coils also generally do not contain repositionable or step-wise release features.

[0005] Consequently, a smaller diameter (lower profile), repositionable implant deployment device that releases an implant into, or upon, a body region in a more precise, continuous or step-wise fashion, without the use of a sheath or balloon would provide significant benefit to patients with various medical conditions.

#### SUMMARY OF THE INVENTION

[0006] The present invention is a low profile implant delivery device that may be deployed without a sheath, and is designed to release portions of implants simultaneously or sequentially.

[0007] In one variation, the implant delivery device includes a noninflatable, elongate delivery guide member configured to direct at least one implant to an anatomical treatment site, at least one implant that surrounds at least a portion of the delivery guide, and at least one releasable joint configured to maintain at least a section of the at least one implant in contact with the delivery guide member until release of the at least one releasable joint. The at least one releasable joint may

provide contact on the delivery guide member at the implant distal end, its proximal end, or at any position therebetween.

[0008] The implant may be a helical scaffold, e.g., a stent, in particular, a self-expandable stent, or it may be an occlusive coil. The implant may be symmetric or asymmetric. In some instances, the implant delivers a therapeutic agent.

[0009] The delivery guide member may include a wire and/or a tubular member having a lumen. If desired, a radioopaque marker may be included on the delivery guide to aid with its placement. When designed to include a tubular member, it co-axially surrounds at least a portion of the delivery guide, and works as a tubular actuator configured to release at least one releasable joint upon distal axial movement along the delivery guide member.

[0010] In another variation, the implant delivery device includes an actuator slidably located at least partially within the delivery guide member and is configured to mechanically release at least one releasable joint upon axial movement of the actuator within the delivery guide member. In other variations, the actuator may also release at least one releasable joint upon rotational movement of the actuator, upon the application of fluid pressure in the delivery guide member lumen, or upon application of a suitable DC current to the at least one releasable joint. Release of the releasable joints using any one of the release mechanisms described above may be sequential, if precise positioning is required, or may be simultaneous.

[0011] The implant delivery device may be included in a system for implant delivery which further employs one or more embolic filters at either the proximal or distal section of the delivery guide, or at both the proximal and distal sections of the delivery guide.

[0012] The system may be used for implant delivery into lumens of tubular organs including, but not limited to, blood vessels (including intracranial vessels, large vessels, peripheral vessels, adjacent aneurysms, arteriovenous malformations, arteriovenous fistulas), ureters, bile ducts, fallopian tubes, cardiac chambers, ducts

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such as bile ducts and mammary ducts, large and small airways, and hollow organs, e.g., stomach, intestines, and bladder. The implant may be of a design that is of a size that is smaller during delivery and larger after implantation. The design may be used to provide or to maintain patency in an open region of an anatomical structure, or to occlude a site, or to isolate a region (e.g., to close an aneurysm by blocking the aneurysm opening or neck by placement in an adjacent anatomical structure such as an artery or gastrointestinal tubular member), or to corral or collect a number of occlusive devices (e.g., coils or hydratable polymeric noodles) or compositions at a site to be occluded or supported. The system may also be employed for implant delivery into solid organs or tissues including, but not limited to, skin, muscle, fat, brain, liver, kidneys, spleen, and benign and malignant tumors. Preferably, the implant is delivered to a target site in a blood vessel lumen.

#### BRIEF DESCRIPTION OF THE DRAWING(S)

[0013] Figure 1A is a side view of an implant delivery device with a partial cross-section of the distal section of the delivery guide.

[0014] Figure 1B is a cross-sectional view of the delivery guide and implant taken at line 1B-1B in Figure 1A.

[0015] Figure 2 is a side view of an implant delivery device having a tubular member (actuator) attached to the proximal implant end with a partial cross-section of the distal section of the delivery guide.

[0016] Figure 3A is a side view of the implant in Figure 2 being expanded by distally moving the tubular member towards the distal section of the delivery guide.

[0017] Figure 3B is a longitudinal cross-sectional view of a distal implant release mechanism.

[0018] Figures 3C<sub>1</sub> and 3C<sub>2</sub> are longitudinal cross-sectional views of an implant delivery device having a mechanical release mechanism for deploying one end of an implant.



[0019] Figures 3D<sub>1</sub>-3D<sub>3</sub> are longitudinal cross-sectional views of an implant delivery device having a mechanical release mechanism for independently releasing the implant ends.

[0020] Figures 3E<sub>1</sub>-3E<sub>4</sub> are longitudinal cross-sectional views of an implant delivery device having a hydraulic release mechanism for independently releasing the implant ends.

[0021] Figures 3F<sub>1</sub>-3F<sub>2</sub> are longitudinal cross-sectional views of a variation of the hydraulic release mechanism described in 3E<sub>1</sub>-3E<sub>4</sub>.

[0022] Figures 3G<sub>1</sub>-3G<sub>3</sub> are longitudinal cross-sectional views of an implant delivery device having a mechanical release mechanism according to another variation of the invention.

[0023] Figure 4 is a longitudinal cross-sectional view of an implant delivery device having a mechanical release mechanism according to yet another variation of the invention.

[0024] Figures 5A-5C are longitudinal cross-sectional views of an implant delivery device having an electrolytic implant release mechanism.

[0025] Figure 5D shows a longitudinal cross-sectional view of an implant delivery device having an electrolytic release mechanism according to another variation of the invention.

[0026] Figure 5E shows a longitudinal cross-sectional view of an implant delivery device having a thermal release mechanism according to one variation of the invention.

[0027] Figures 6A-6D show the general method for serially releasing an implant at a target site.

#### DETAILED DESCRIPTION OF THE INVENTION

[0028] Described here are devices, systems, and methods for delivering implants into both open and solid regions of the body. The term "region" as used

herein refers to luminal structures as well as solid organs and solid tissues of the body, whether in their diseased or nondiseased state. Examples of luminal structures include, but are not limited to, blood vessels, arteriovenous malformations, aneurysms, arteriovenous fistulas, cardiac chambers, ducts such as bile ducts and mammary ducts, fallopian tubes, ureters, large and small airways, and hollow organs, e.g., stomach, intestines, and bladder. Solid organs or tissues include, but are not limited to, skin, muscle, fat, brain, liver, kidneys, spleen, and benign and malignant tumors. The device assembly generally includes an elongate, perhaps solid delivery guide, an implant, and one or more implant release mechanisms.

#### Delivery Guide

[0029] The delivery guide is elongate and has a comparatively small effective diameter. It has the function of permitting delivery of the implant to a selected site and supporting the implant in a collapsed form during positioning and implantation. The delivery guide is usually noninflatable. It may also be solid, or may have a lumen extending therethrough, depending on such factors as the degree of flexibility required, type of associated release mechanism, the constitution material, and the like. The tip of the delivery guide may be tapered and/or straight, curved, or j-shaped, depending on factors such as physician preference, the anatomy of the tubular organ or region of interest, degree of stiffness required, and the like. The delivery guide may or may not include an outer spring coil, for, e.g., fluoroscopic visualization.

[0030] The delivery guide may be made from any biocompatible material including, but not limited to, stainless steel and any of its alloys; titanium alloys, e.g., nickel-titanium alloys; other shape memory alloys; tantalum; polymers, e.g., polyethylene and copolymers thereof, polyethylene terephthalate or copolymers thereof, nylon, silicone, polyurethanes, fluoropolymers, poly (vinylchloride), and combinations thereof. The diameter of the delivery guide may usually be about 0.013

cm to about 0.130 cm (about 0.005 inches to about 0.05 inches), more usually about 0.013 cm to about 0.076 cm (about 0.005 inches to about 0.03 inches), and more usually still about 0.015 cm to about 0.030 cm (about 0.006 inches to about 0.012 inches). In a preferred variation, the diameter of the delivery guide is approximately about 0.020 cm (about 0.008 inches).

[0031] A lubricious coating may be placed on the delivery guide if desired to facilitate advancement of the delivery guide. The lubricious coating typically will include hydrophilic polymers such as polyvinylpyrrolidone-based compositions, fluoropolymers such as tetrafluoroethylene, or silicones. In one variation, the lubricious coating may constitute a hydrophilic gel. Furthermore, the delivery guide may include one or more radioopaque markers that indicates the location of the distal section of the delivery guide upon radiographic imaging. Usually, the marker will be detected by fluoroscopy.

### Implants

[0032] The implant itself may be of a shape tailored to achieve a specific purpose. As noted elsewhere, if the purpose of the implant is to provide or to maintain patency of an anatomical structure such as an artery or duct, the implant shape after implantation is itself tubular. The shape may be symmetric or asymmetric, as the purpose dictates.

[0033] Other shapes, including cage structures, may be used to provide patency to vessels or to act as collecting or coralling structures for occlusive members or materials.

[0034] If the purpose or task is to occlude a lumen or open region, the implant may have the form of an occlusive coil that remains helical after deployment or assumes a random orientation.

[0035] In one variation, the implant for placement into a luminal structure is a helical scaffold, e.g., a stent, but any scaffold shape that maintains patency of a lumen

may be used. The stents are typically self-expanding stents, such as described in U.S. 4,768,507 to Fishell et al., U.S. 4,990,155 to Wilkoff et al., and U.S. 4,553,545 to Maass et al. In another variation, the implant is an occlusive member, e.g., an occlusive coil, such as described in U.S. 5,334,210 to Gianturco and U.S. 5,382,259 to Phelps et al.

[0036] The interior and exterior surfaces of the implant may be designed to prevent the activation of pathological processes during or after implant deployment. For example, in the case of a vascular stent, the exterior stent surface may be formed to be smooth to decrease the likelihood of intimal damage upon stent release (which would trigger the inflammatory process and attract atheromatous plaque-forming cells). The interior stent surface may also be smooth to minimize turbulent flow through the stent and decrease the risk of stent thrombosis.

[0037] Important physical properties of the implant to consider include, but are not limited to: length, (stent) diameter in the expanded state, degree of flexibility and lateral stiffness, and the like. These physical properties will be modified to account for such factors as lumen diameter, length of any stenosis, type of luminal structure, or solid organ or tissue involved.

[0038] Metals such as stainless steel and tantalum, or metal alloys such as alloys of nickel and titanium, specifically including superelastic alloys such as NITINOL or Elgiloy which are commonly used by those of skill in the art, may be used to form the implants. However, the implants may also be made from biodegradable polymers, e.g., copolymers of lactic and glycolic acid, or nonbiodegradable polymers, e.g., copolymers of ethylene and vinyl acetate.

[0039] The implants may also include a therapeutic agent. Examples of therapeutic agents that may be used in the implants include, but are not limited to, antibiotics, anticoagulants, antifungal agents, anti-inflammatory agents, antineoplastic agents, antithrombotic agents, endothelialization promoting agents, free radical

scavengers, immunosuppressive agents, thrombolytic agents, and any combination thereof. If the implant is a stent, an antithrombotic agent is preferably included.

[0040] Examples of selective antithrombotic agents include acetylsalicylic acid, argatroban, cilostazol, copidogrel, cloricromen, dalteparin, daltroban, defibrotide, dipyridamole, enoxaparin, epoprostenol, indobufen, iloprost, integrelin, isbogrel, lamifiban, lamoparan, nadroparin, ozagrel, picotamide, plafibride, reviparin sodium, ridogrel, sulfinpyrazone, taprostene, ticlopidine, tinzaparin, tirofiban, triflusal, and any of their derivatives.

[0041] The therapeutic agent may be coated onto the implant, mixed with a biodegradable polymer or other suitable temporary carrier and then coated onto the implant, or, when the implant is made from a polymeric material, dispersed throughout the polymer.

[0042] The implant may include a radioactive material. The radioactive material may be selected on the basis of its use. For instance, the material may be included in an implant where the implant is in the form of a stent that is to be situated over a vascular stenosis. The radioactivity lowers the incidence of re-stenosis. Additionally, the radioactivity may serve the function of a tracer, to allow detection of the location of the implant during the procedure or anytime thereafter. Suitable radioactive tracers include isotopes of gallium, iodine, technetium, and thallium.

#### Release Mechanism

[0043] In one variation of the generic implant delivery system, as shown in Figure 1A, the implant delivery system includes a delivery guide 100. Delivery guide 100 has a proximal section 102 and a distal section 104. An implant, in this case depicted as a stent 106, surrounds a portion of the distal section 104 of the delivery guide, and is releasably attached to the distal section 104 of the delivery guide. The implant 106, as shown in Figure 1B, is concentrically adjacent to the delivery guide 100. Although I show the stent in Figure 1A and 1B as the implant (106), I depict it

in this fashion solely for the illustrative purpose of indicating the siting of the implant 106 on the delivery guide 100 with the distal and proximal implant release mechanism (109, 111). Various implant release mechanisms or structures are discussed in greater detail below.

[0044] Implant 106 is shown to be directly attached to, is contiguous to, the delivery guide 100 at the proximal end 108 of the implant and distal end 110 of the implant. In the system shown in Figure 1A, implant 106 may be secured to the delivery guide 100 by such generic controllably releasable mechanisms as mechanical, thermal, hydraulic, and electrolytic mechanisms, or a combination thereof. Examples of these release mechanisms will be discussed below.

[0045] Consequently, release of the implant 106 from the delivery guide 100 may be achieved through a mechanical detachment process involving, e.g., twisting of the delivery guide, such as described by Amplatz in U.S. 6,468,301, or translational movement of the delivery guide in relation to the implant. Implant release may also be achieved using a thermally detachable joint, such as described in U.S. 5,108,407 to Geremia et al., an electrolytic detachable joint, such as described in U.S. 5,122,136 and U.S. 5,354,295, both to Gulglielmi et al., or a combination thereof.

[0046] In another variation, and as shown in Figure 2, the system includes a tubular member 200 co-axially mounted on a delivery guide 202. Tubular member 200 may form a component of the delivery guide 202 that cooperates with one or more of the releasable mentioned joints on the implant (209, 211) to release those joints (and therefore, release the implant 204) upon application of a releasing movement, axial or twisting. An implant, e.g., a stent 204, is mounted on a distal section 206 of the delivery guide and the distal end 208 of the tubular member is attached to the proximal end 210 of the stent. The distal end 212 of the stent is attached using a releasable joint 211 to the distal section 206 of the delivery guide 202.

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[0047] As mentioned above, I may use a tubular member mounted coaxially about the delivery guide, that slides axially about that delivery guide, as an actuator to release the implant. The outer tubular member may also be used to pre-position the implant. For instance, prior to release, the outer tubular member may be used to expand the implant to therefore obscure its placement, and so to permit adjustment of the placement. Figure 3A shows a stent 300 expanding as tubular member 302 is moved distally on the delivery guide 304, in the direction of the arrow. The stent is then released from the delivery guide. Specifically, the distal end 306 of the stent is released from a distal section 308 of the delivery guide, followed by release of the proximal end 310 of the stent from the distal end 312 of the tubular member. As mentioned above, the stent 300 may be secured to a distal section 308 of the delivery guide by such mechanisms as lock and key arrangements, biocompatible adhesives, soldering, or a combination thereof. Consequently, stent release may be achieved through a mechanical detachment process, a thermal detachment process (e.g., by heat produced from an exothermic reaction), an electrolytic detachment process, or a combination thereof.

[0048] Figures 3B and 3C show yet another variation of a stent release mechanism. In Figure 3B, brackets 314 may be used to couple the stent 300 to the distal section 308 of the delivery guide. Separation of the stent 306 from the brackets 314, e.g., by one of the detachment processes mentioned above, releases the distal end 306 of the stent from a distal section 308 of the delivery guide, allowing the stent distal end 306 to expand in the tubular organ.

[0049] Controllable release of an end of an implant from the delivery guide may be accomplished using the structure of Figure 3C<sub>1</sub>. Brackets 314 couple the stent proximal end 310 to the distal region 312 of the tubular member 313 that forms a portion of the delivery guide. The brackets 314 have a ramped region 316 which are proximally adjacent to an enlarged (and perhaps ball- or barrel-shaped) portion 318 of the delivery guide and bracket arms 320. When the actuator 305 is moved

proximally, as shown by the direction of the arrow, the ball-shaped portion 318 forces the ramped regions 316 of the brackets outward from the delivery guide axis, in a radial fashion, causing the bracket arms 320 to be displaced radially outwardly from the proximal end 310 of the stent, thereby releasing the stent proximal end 310.

[0050] Figure 3C<sub>2</sub> shows the results of moving the actuator 305 proximally. The clips (316) have rotated as shown due to the force exerted upon the ramps (317) by the ball (318). The implant (320) has expanded in diameter from that found in its undelivered form.

[0051] Figure 3D<sub>1</sub>, shows a delivery system 319 in which the two ends of the implant 321 may be independently deployed by using an actuator 304 having a proximal releasing ball 322 and a distal releasing ball 327. The two balls are spaced in such a way that, in the variation shown in Figure 3D<sub>1</sub>, the distal ball 327 releases the distal end 331 of implant 321 and the proximal ball 322 then releases the proximal end 329 of implant 321 upon additional proximal movement of actuator 304. This sequence of events is shown in Figs. 3D<sub>1</sub>, 3D<sub>2</sub>, and 3D<sub>3</sub>. The implant 321, is shown to be completely released in Figure 3D<sub>3</sub>. In this variation, the implant 321 may be self-expanding, e.g., constructed of a superelastic alloy such as nitinol or another alloy having high elasticity, e.g., an appropriate stainless steel.

[0052] A structure similar to that shown in Figures 3D<sub>1</sub>, 3D<sub>2</sub>, and 3D<sub>3</sub> may also be used to deploy an implant using fluid pressure as the releasing impetus.

[0053] Figures 3E<sub>1</sub>, 3E<sub>2</sub>, 3E<sub>3</sub> and 3E<sub>4</sub> show a hydraulic variation. Shown are the delivery guide 350, having a hollow lumen 352, a self-expanding implant 354 (shown variously as non-expanded (e.g., in a "first form") in Fig. 3E<sub>1</sub>, partially expanded in Fig. 3E<sub>2</sub>, and fully expanded in Figs. 3E<sub>3</sub> and 3E<sub>4</sub> (e.g., in a "second form")), and an actuator 356 with a sealing member 358 and a radio-opaque member 360.

[0054] The implant 354 (here shown to be a stent or the like) is held to the delivery guide 350 during delivery to the selected treatment site using distal brackets



364 and proximal brackets 362 or clips or the like. The proximal and distal brackets (364, 362) either include regions that cooperate with the fluid in lumen 352 to move upon application of increased pressure in that lumen 352 and release the implant 350 or move in concert with a separate pressure sensitive motion component.

[0055] Figure 3E<sub>1</sub> shows the actuator 356 as the sealing member 358 approaches the various orifices or openings (proximal orifices 366 and distal orifices 368) communicating from the lumen 356 to the hydraulically or fluidly actuatable clips or retaining brackets (proximal brackets 362 and distal brackets 364).

[0056] Included in the description of this variation is a radio-opaque marker 360 on the actuator shaft 356 that allows the user to simply line up that actuator marker 360 with a corresponding radio-opaque marker 370 or the delivery guide 350, increase the pressure in lumen 352 (via syringe, pump, etc.) and deploy the proximal end 371 of implant 354. The interior pressure raises or rotates the proximal clips or brackets 362 and moves them out of contact with the implant 354. Figure 3E<sub>2</sub> shows the movement of the proximal end of implant 354 away from the delivery guide 350.

[0057] Figure 3E<sub>3</sub> shows the axial movement of actuator 356 distally to a position where the sealing member 358 is positioned to actuate distal clips or brackets 364 and release the distal end of implant. Again, a radio-opaque marker 374 (perhaps with an additional identification band 376) has been depicted to show alignment of the radio-opaque marker or band 360 on the actuator shaft 356 prior to the increase in pressure for deployment.

[0058] Figure 3E<sub>4</sub> shows final deployment at the implant 354 and proximal movement at the actuator 356, just prior to withdrawal of the delivery guide 350. The distal and proximal clips or brackets (362, 364) have relaxed to the surface of the delivery guide 350.

[0059] Alternatives to certain of the elements shown in the variation found in Figs. 3E<sub>1</sub> to 3E<sub>4</sub> is seen in Figs. 3F<sub>1</sub> and 3F<sub>2</sub> and includes, e.g., a cover element 380 to block or cover proximal orifices 366 during the pressurization of the distal orifices

368. The cover element 380 includes holes 382 to allow fluid flow past the cover element 380.

[0060] Fig. 3G<sub>1</sub> shows a variation of the described system in which an implant or stent 371 is maintained in position on a hollow delivery guide 373 using spring clips 375 proximally and 377 distally. The spring clips hold the implant 371 in place during delivery and against guide member 373. An actuator 379 is used to remove the clips 375, 377 sequentially and to release each end of implant 371 in an independent fashion. Clips 375 and 377, after actuation or release, remain interior to the guide member 373 for later removal with that guide member. The system shown in Figures 3G<sub>1</sub>, 3G<sub>2</sub> and 3G<sub>3</sub> may be used to deliver a number of implants in a sequential fashion. Since the retainer clips 375, 377 remain within the guide member 373 after delivery, the actuator 379 is able to slide past the site on guide member 373 where the clips 375, 377 resided prior to implant 371 deployment, down to and distally to a site on the guide member having another implant for subsequent delivery. Consequently, an arrangement such as this may be used to deploy, in a sequential fashion, a number of stents or the like without withdrawal of the guide member.

[0061] In the variation shown in Figs. 3G<sub>1</sub>, 3G<sub>2</sub> and 3G<sub>3</sub>, the clips 375 and 377 are spring-biased to collapse within the lumen 381 of the guide member 373 once they are pushed into the respective slots 383 provided for such retraction. Such spring loaded clips retain the self expanding stent or implant 371 onto the face of guide member 373. Each of clips 375, 377 are shown in this variation to have hook members 387, 389 that engage the implant 371, often axially stretching the implant 371 and maintaining the delivery radius of the implant 371 as shown.

[0062] As shown in Fig. 3G<sub>1</sub>, actuator 379 is pushed distally along the outer surface of guide member 373 until it contacts the proximal end of clip 375. Further distal movement of actuator 379 urges clip 375 into lumen 381 thereby rotating horn 387 out of cooperating receptacle area in implant 371.

[0063] Fig. 3G<sub>2</sub> shows the results of such movement after clip 375 has completed its springed closure within lumen 381. As shown in that Figure, the proximal end of implant 371 has expanded and yet the distal end of implant 371 remains closed and hooked to distal clip 377. This semi-open condition allows for some adjustment of the implant if needed. Fig. 3G<sub>3</sub> shows the results of additional distal movement of actuator 379 until it contacts distal clip 377 (shown in Fig 3G<sub>3</sub> in its collapsed form ) and thereby allowing the distal end of implant 371 to self-expand into the chosen treatment site.

[0064] Fig. 3G<sub>3</sub> shows that guide member 379 is free. Implant 371 is shown in its self expanded form no longer adjacent the central guide member 379. Actuator 379 is situated within implant 371 and is no longer in contact with proximal clip 375 nor distal clip 377. Actuator 379 is thus able to continue distally to another implant containing site positioned in a more distal site on the guide member 373.

[0065] The mechanical variation shown in Figs. 3G<sub>1</sub>, 3G<sub>2</sub>, 3G<sub>3</sub> may be modified in such a way that the actuator is interior to the lumen of the guide member and deploys the implant upon distal movement of the actuator by providing an actuator with a slot or other "room-making" provisions in the actuator. The actuator and any retained clips would then be used to actuate the clips in the next more distal implant if so desired.

[0066] In yet a further variation, the system releases an implant (shown as a stent 404 in Fig. 4) attached to a delivery guide 400 by one or more attachment arms 402 positioned, e.g., at the implant proximal and distal ends, by sliding a tubular member 406, mounted co-axially on the delivery guide 400, distally over the delivery guide 400. The stent 404 is secured to the delivery guide 400 when the attachment arms 402 are in a radially expanded configuration (as illustrated in Figure 4). The tubular member 406 urges the attachment arms 402 into a compressed configuration as it slides distally over the delivery guide 400, in the direction of the arrow. When the attachment arms 402 are compressed by the tubular member 406, they are moved

inward from the stent 404, toward the central axis of the delivery guide 400, thereby releasing the stent 404 from the delivery guide 400. Stent detachment occurs in a serial fashion as the tubular member 406 is moved distally, with detachment of the stent proximal end 408 occurring before detachment at the stent distal end 410. Consequently, if the stent position requires readjustment after detachment of the stent proximal end, the stent may be repositioned prior to detaching the stent distal end. In one variation, the tubular member is a balloon catheter.

[0067] The attachment arms 402 are generally made from the same materials as the delivery guide 400, e.g., stainless steel or nickel-titanium alloy, and will typically have a length, thickness, shape, and flexibility appropriate for its intended mechanism of release. The distal ends 412 of the attachment arms may be of any design, so long as one or more of them, when in a radially expanded configuration, secures a portion of a stent to a delivery guide, and when in a compressed configuration, releases that same stent portion from the delivery guide.

[0068] The tubular member may be a thin-walled tube (e.g., approximately 0.005 cm (0.002 inches) in thickness) with an outside diameter ranging from about 0.025 cm to about 0.139 cm (0.010 inches to about 0.055 inches), more usually from about 0.025 cm to about 0.05 cm (0.010 inches to about 0.020 inches), and more usually still from about 0.025 cm to about 0.035 cm (0.010 inches to about 0.014 inches). Depending on such factors as degree of flexibility or durometer required, they may be made from various metals or metal alloys, including, but not limited to, stainless steel and nickel-titanium alloy, or from various polymers, such as polyvinyl chloride, polyethylene, polyethylene terephthalate, and polyurethane.

[0069] Figures 5A, 5B, and 5C show a variation of the described delivery system 500 in which a member of electrolytic delivery joints are used to deploy an implant 502, such as a stent.

[0070] The electrolytic delivery joints shown here (e.g., 504 in Figure 5C) are well known as controllable delivery joints for placement of vaso-occlusive coils. One

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such commercially available device using an electrolytically detachable joint is sold by Target Therapeutics, a subsidiary of Boston Scientific Corp., as the Guglielmi Detachable Coil (or "GDC"). Numerous patents to Dr. Guglielmi describe the theory of its use.

[0071] In essence, the electrolytically erodible joint is a section of an electrical circuit that is not insulated and is of a metallic material that does not form insulating oxides when exposed to an aqueous environment (e.g., aluminum and tantalum) and is sufficiently "non-noble" that it will either electrolytically erode by ionic dissolution into an anatomical fluid or, perhaps, electrochemically erode by forming readily soluble oxides or salts.

[0072] The erodible joint 504 shown in Figure 5C is a bare metal of a size, diameter, etc. that erodes away when a current is applied to insulated wire 506. The current flow is from a power supply through insulated wire 506, bare joint 504, into the ionic anatomical fluid surrounding the site to be treated, and back to a return electrode situated perhaps on the patient's skin and then back to the power supply. The current flows through the circuit so long as the joint 504 exists.

[0073] With that background, Figure 5A shows a device having several joints (504, 508, 510, 512) that each may be independently severed to controllably deploy the implant 502. Implant 502 is shown having coils (514, 516) that are terminated at each end by an erodible joint and that, prior to the severing of a joint, hold this implant 502 to the surface of the delivery member 520. The implant 500 is self-expanding, once released. The wires forming the two coils in this variation slide within the implant or "uncoil" and thereby allow the implant body itself to expand. The coils may comprise (if electrically connected to the erodible joint) a metal that is higher in the Mendeleev Electromotive Series than is the composition at the electrolytic joint or the coils may comprise a polymer that may be bio-erodible or not.

[0074] In any case, a suitable way to assure that the coils (514, 516) maintain the low profile of the implant 502 during delivery is via the placement of the various

conductive wires (506, 516, 518, 520) through the adjacent holes (524, 526, 528) and fill the holes with e.g., an epoxy to hold all in place. Independently causing current to flow through each of the joints will release the implant in the region of the released joint. Once all joints are eroded, the implant is released.

[0075] Although release from proximal and distal ends of the tubular form of the implants has been described, detachment from a delivery guide is not so limited. In another variation, the stent is attached to the delivery guide at one or more positions along the length of the stent, in addition to attachment at the proximal and distal implant ends. Once the distal stent end is released, the additional attachments may be independently released until detachment at the proximal implant end releases the implant entirely from the delivery guide. Serial release may provide better control of positioning in tubular organs.

[0076] Figs. 5D and 5E show in more detail, the components of an electrolytic joint (as may be found in Figs 5A, 5B and 5C) and another electrically actuated joint using a meltable or softenable or polymerically sizable joint.

[0077] Fig. 5D shows the insulated wire 524 with insulation 523 and conductor 525. The electrolytic joint 504 is also shown. In this variation, the wire 524 is shown to be secured into the delivery guide wall 520 by, e.g., an epoxy 527, an alternative or cooperative band or component 529 holding the wire 524 to the surface of guide member 520 is also shown. After erodable joint 504 is eroded, the implant of 502 expands and leaves the securement band 529 on the delivery guide 520.

[0078] Fig. 5E shows a similar variation but the joint comprises a thermoplastic adhesive or shape changing polymer 531 situated on the end of wire 525 and within a cup or other receptacle 533. The adhesive is of the type that changes form or viscosity upon application of current to the joint. In this variation, the thermoplastic is rendered conductive, but resistive, by introduction of material such as carbon black into the polymeric adhesive. As soon as the polymer changes its

shape, form, or phase, the implant expands to the desired form about the central guide member 520 again, the wire may be held in place with an adhesive 527 if so desired.

[0079] Although the figures show wires and other remnants of the joints remaining exterior to the central guide member 520 and the others shown and described here, it is desirable that these not be situated in such a way that they will harm the tissues into which they are placed.

#### Delivery Method

[0080] The implant delivery devices described herewith may include multiple implants on a single delivery guide or may be used in conjunction with other instruments, as seen appropriate, to treat the target site. In general, the tubular organ of interest is percutaneously accessed, but the method of accessing will usually be dependent on the anatomy of the organ, medical condition being treated, health status of the subject, and the like. Consequently, access by a laparoscopic or open procedure may also be obtained.

[0081] Figures 6A-6D show the general method of deploying a stent using my described system. After obtaining access to the tubular organ of interest 600 (blood vessel in Figure 6A), a delivery guide 602 is placed through the selected area of stenosis 604 at the target site. A balloon catheter 606 is then advanced over the delivery guide 602, and balloon angioplasty performed to dilate the area of stenosis 604 (Figure 6B). The balloon catheter 606 is then retracted proximally and the delivery guide 602 exchanged for a stent delivery device 608 (Figure 6C). Appropriate placement of the stent is guided by radioopaque markers 616 on the delivery guide 612. The distal end 610 of the stent is then released from the delivery guide 612. At this point, stent position may again be checked by verifying the location of the radioopaque markers. The proximal stent end 614 is then released from the delivery guide 612.

[0082] If desired, an embolic filter may be used during stent deployment to filter any debris generated during the procedure. The filter will usually be attached to the delivery guide such that it filters debris distal to the stent, but may also be attached to the delivery guide proximal to the stent, or both distal and proximal to the stent. The filter may be of any design, as long as it does not affect the substantially atraumatic, low profile, and controlled release characteristics of the stent delivery device. Typically, the filter is basket-shaped, and made from a shape-memory material, e.g., an alloy of titanium and nickel. The filter will usually be contained within the balloon catheter lumen, and deployed to its pre-designed shape once the balloon catheter is removed. Following placement of the stent, the balloon catheter may be advanced over the delivery guide to enclose the filter with any accumulated debris. The balloon catheter, filter, and delivery guide may then be removed from the body.

#### Applications

[0083] The implant delivery system may be used in mammalian subjects, preferably humans. Mammals include, but are not limited to, primates, farm animals, sport animals, cats, dogs, rabbits, mice, and rats.

[0084] The system may be employed for implant delivery into lumens of tubular organs including, but not limited to, blood vessels (including intracranial vessels, large vessels, peripheral vessels, aneurysms, arteriovenous malformations, arteriovenous fistulas), ureters, bile ducts, fallopian tubes, cardiac chambers, ducts such as bile ducts and mammary ducts, large and small airways, and hollow organs, e.g., stomach, intestines, and bladder. The system may also be employed for implant delivery into solid organs or tissues including, but not limited to, skin, muscle, fat, brain, liver, kidneys, spleen, and benign and malignant tumors. Preferably, the implant is delivered to a target site in a blood vessel lumen.



[0085] Clinically, the system may generally be used to treat stenosis of various tubular organs, arising from such etiologies as atherosclerosis, autoimmune conditions, scarring, or exterior compression, e.g., as may be seen with a neoplastic process. The system may also be used to treat medical conditions in which luminal occlusion is desired, e.g., to treat aneurysms, arteriovenous fistulas, and arteriovenous malformations. Furthermore, the system may be employed to deliver implants into such areas as joint spaces, spinal discs, and the intraperitoneal or extraperitoneal spaces.

\* \* \*

All publications, patents, and patent applications cited herein are hereby incorporated by reference in their entirety for all purposes to the same extent as if each individual publication, patent, or patent application were specifically and individually indicated to be so incorporated by reference. Although the foregoing invention has been described in some detail by way of illustration and example for purposes of clarity of understanding, it will be readily apparent to those of ordinary skill in the art in light of the teachings of this invention that certain changes and modifications may be made thereto without departing from the spirit and scope of the appended claims.

## CLAIMS

1. An implant delivery device comprising:
  - a.) a noninflatable, elongate delivery guide member configured to direct at least one implant having an exterior and interior surface to an anatomical treatment site,
  - b.) the at least one implant surrounding at least a portion of the delivery guide member, and
  - c.) at least one releasable joint configured to maintain at least a section of the at least one implant in contact with the delivery guide member until release of the at least one releasable joint.
2. The device of claim 1 wherein the at least one implant comprises exactly one implant.
3. The device of claim 1 wherein the at least one implant comprises more than one implant.
4. The device of claim 1 wherein the delivery guide member comprises a distal section and a proximal section and the at least one implant comprises a distal end and a proximal end and wherein at least one releasable joint maintains an implant distal end in contact with the delivery guide member distal section.
5. The device of claim 4 wherein at least one releasable joint maintains an implant proximal end in contact with the delivery guide member.
6. The device of claim 1 wherein the delivery guide member comprises a distal section and a proximal section and the at least one implant comprises a distal end and

a proximal end and wherein at least one releasable joint maintains an implant proximal end in contact with the delivery guide member.

7. The device of claim 1 wherein the delivery guide member comprises a wire.
8. The device of claim 7 further comprising a tubular actuator co-axially surrounding at least a portion of the delivery guide and configured to release at least one releasable joint upon distal axial movement along the delivery guide member.
9. The device of claim 1 further comprising a tubular actuator co-axially surrounding at least a portion of the delivery guide and configured to release at least one releasable joint upon distal axial movement along the delivery guide member.
10. The device of claim 1 wherein the delivery guide member comprises a tubular member having a lumen.
11. The device of claim 10 further comprising an actuator slidably located at least partially within the delivery guide member lumen and configured to release at least one releasable joint upon axial movement within the delivery guide member.
12. The device of claim 11 wherein the actuator is configured to sequentially release more than one releasable joint upon axial movement within the delivery guide member.
13. The device of claim 11 wherein the actuator is configured to simultaneously release more than one releasable joint upon axial movement within the delivery guide member.

14. The device of claim 10 further comprising an actuator slidably located at least partially within the delivery guide member lumen and configured to release at least one releasable joint upon rotational movement within the delivery guide member.
15. The device of claim 14 wherein the actuator is configured to sequentially release more than one releasable joint upon rotational movement within the delivery guide member.
16. The device of claim 14 wherein the actuator is configured to simultaneously release more than one releasable joint upon rotational movement within the delivery guide member.
17. The device of claim 10 wherein the at least one releasable joint is configured to release upon application of fluid pressure in the delivery guide member lumen and further comprising a fluid director slidably located at least partially within the delivery guide member lumen and configured to direct fluid to and to release that selected at least one releasable joint.
18. The device of claim 17 wherein the fluid director is configured to sequentially release more than one releasable joint upon application of fluid pressure in the delivery guide member lumen.
19. The device of claim 17 wherein the fluid director is configured to simultaneously release more than one releasable joint upon application of fluid pressure in the delivery guide member lumen.
20. The device of claim 10 wherein the at least one releasable joint is configured to release upon application of a suitable DC current to the at least one releasable joint

and further comprising an electrical conductor located at least partially within the delivery guide member lumen to supply said suitable DC current to and to thereby release at least one releasable joint.

21. The device of claim 20 wherein the at least one releasable joints and electrical conductors are configured to sequentially release more than one releasable joint.

22. The device of claim 20 wherein the at least one releasable joints and electrical conductors are configured to simultaneously release more than one releasable joint.

23. The device of claim 1 wherein the implant is a stent.

24. The device of claim 23 wherein the stent is unsheathed.

25. The device of claim 1 wherein the implant is an occlusive coil.

26. The device of claim 1 wherein the implant further comprises a therapeutic agent.

27. The device of claim 26 wherein the therapeutic agent is selected from the group consisting of antibiotics, anticoagulants, antifungal agents, anti-inflammatory agents, antineoplastic agents, antithrombotic agents, endothelialization promoting agents, free radical scavengers, immunosuppressive agents, thrombolytic agents, and combinations thereof.

28. The device of claim 1 wherein the delivery guide further comprises a radioopaque marker.

29. The device of claim 8 wherein the hollow shaft is a balloon catheter.
30. A system for delivering an implant to a target site in a tubular organ comprising:
  - a) the device of any one of claims 1-29; and
  - b) a balloon catheter.
31. The system of claim 30 further comprising an embolic filter.
32. The system of claim 31 wherein the embolic filter is attached to the proximal end of the delivery guide.
33. The system of claim 30 wherein the implant is a stent.
34. The system of claim 30 wherein the implant is an occlusive coil.
35. A method for delivering an implant in a subject comprising:
  - a) accessing a body region;
  - b) advancing the device of any one of claims 1-29 to a target site in the body region; and
  - c) releasing the implant at the target site.
36. The method of claim 35 further comprising the step of deploying at least one embolic filter.
37. The method of claim 35 wherein the step of releasing comprises detaching the distal end of the implant from the delivery guide before detaching the proximal end of the implant from the delivery guide.

38. The method of claim 35 wherein the step of releasing comprises a mechanical detachment process.
39. The method of claim 35 wherein the step of releasing comprises a hydraulic detachment process.
40. The method of claim 35 wherein the step of releasing comprises an electrolytic detachment process.
41. The method of claim 35 wherein the body region is a tubular or hollow organ.
42. The method of claim 41 wherein the tubular or hollow organ is selected from the group consisting of blood vessels, arteriovenous malformations, aneurysms, arteriovenous fistulas, cardiac chambers, bile ducts, mammary ducts, fallopian tubes, ureters, large and small airways, stomach, intestines, and bladder.
43. The method of claim 35 wherein the body region is a blood vessel.
44. The method of claim 35 wherein the implant is a stent.
45. The method of claim 35 wherein the implant is an occlusive coil.
46. The method of claim 35 wherein the target site comprises an aneurysm.
47. The method of claim 35 wherein the subject is human.
48. The method of claim 35 wherein the step of accessing is percutaneous.

49. The device of claim 1 wherein the implant exterior surface is smooth after deployment.

50. The device of claim 1 wherein the implant interior surface is smooth after deployment.



#### ABSTRACT OF THE DISCLOSURE

The invention provides an atraumatic, low profile device for the delivery of one or more implants into tubular organs or open regions of the body. The implant delivery device may simultaneously or independently release portions of the implant, e.g., the proximal and distal ends of the implant. This independent release feature allows better implant positioning at the target site. Upon deployment, the implants may be placed at the target site without a sheath.

FIGURE 1A

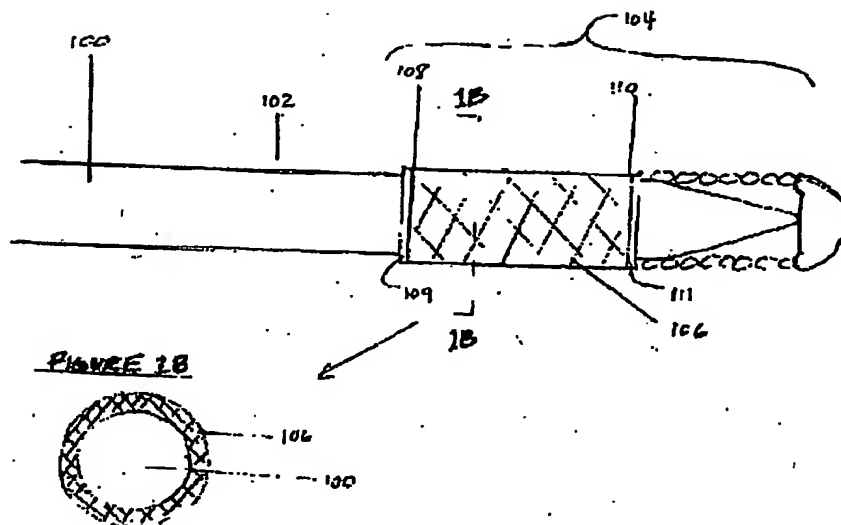


FIGURE 2

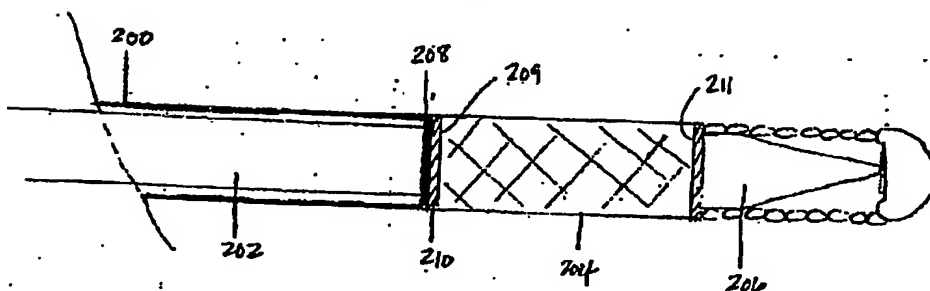


FIGURE 3A

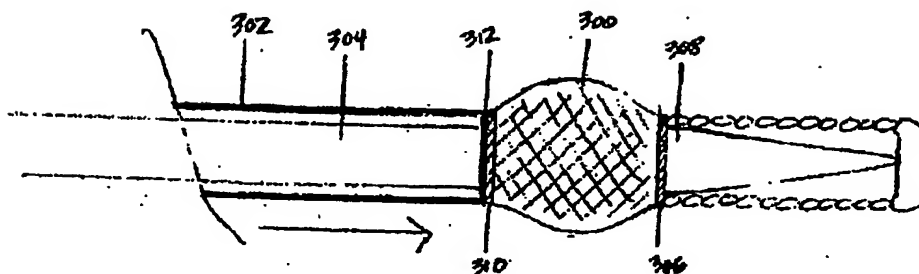


FIGURE 3B

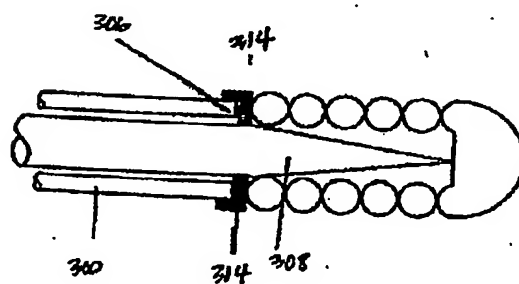


FIGURE 3C<sub>1</sub>

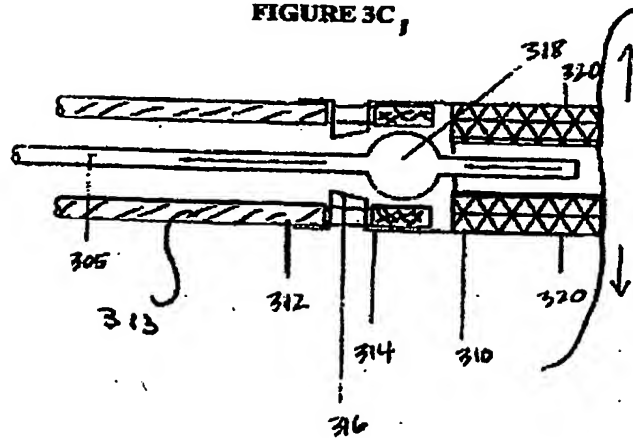
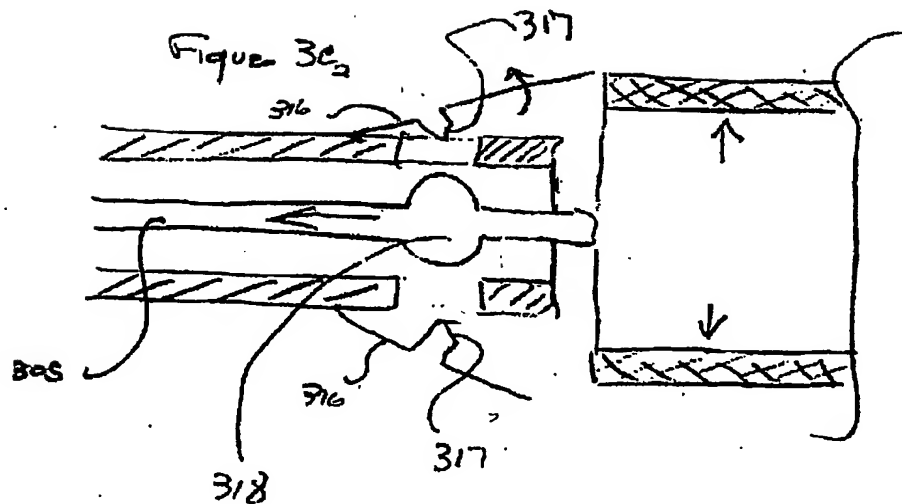
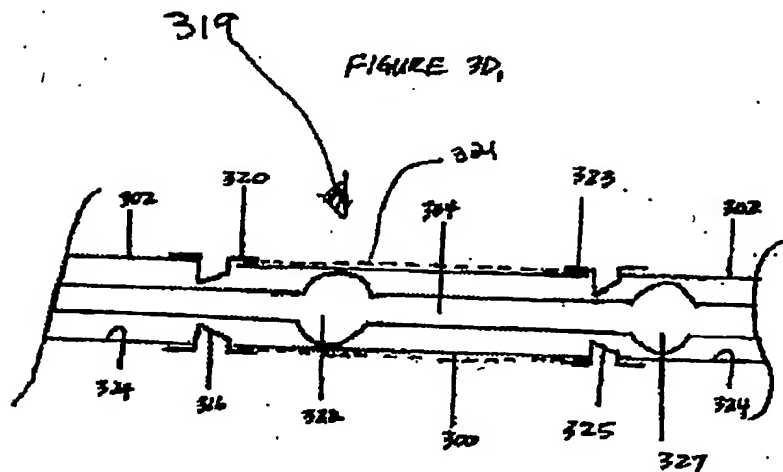
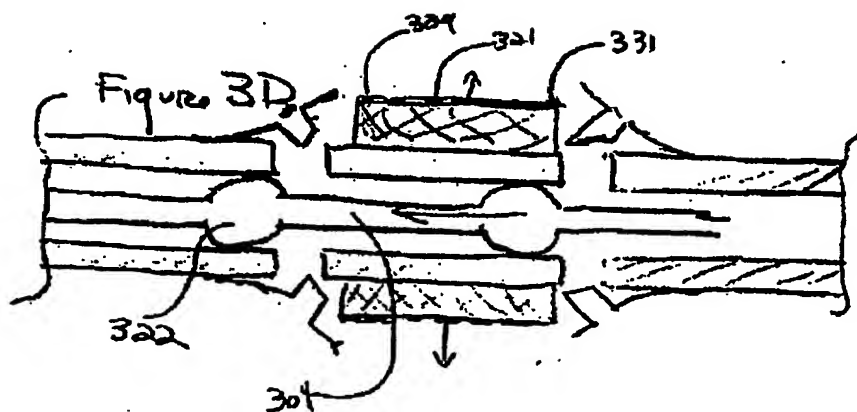
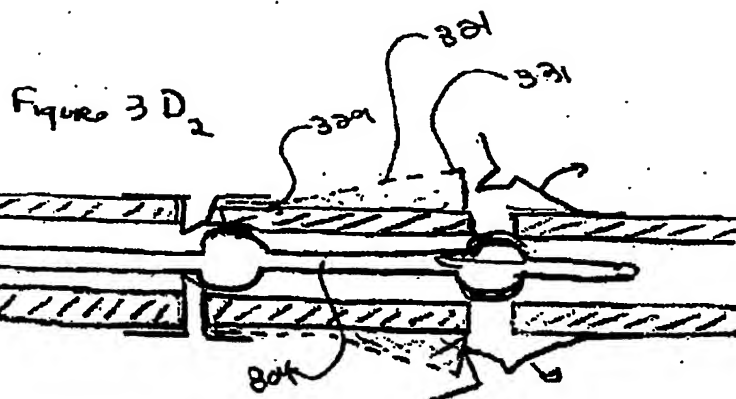
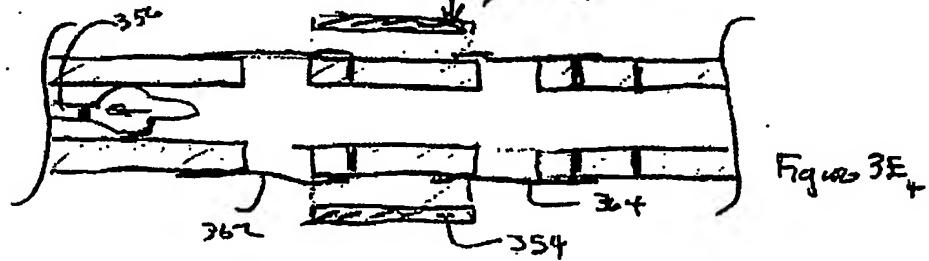
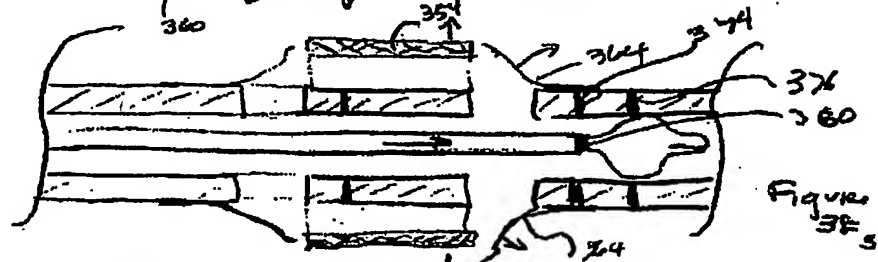
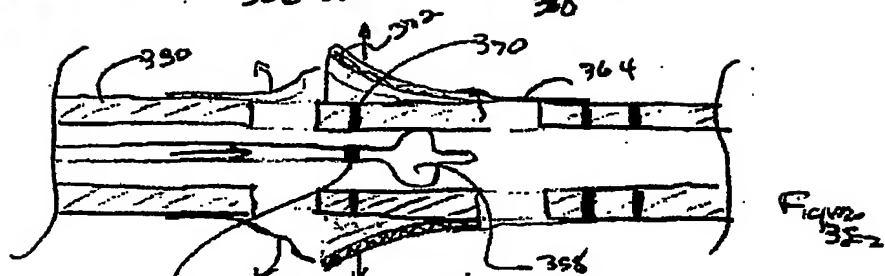
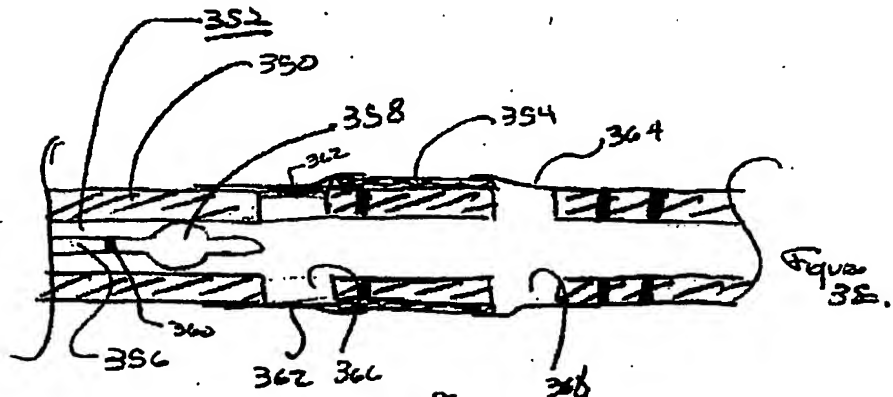


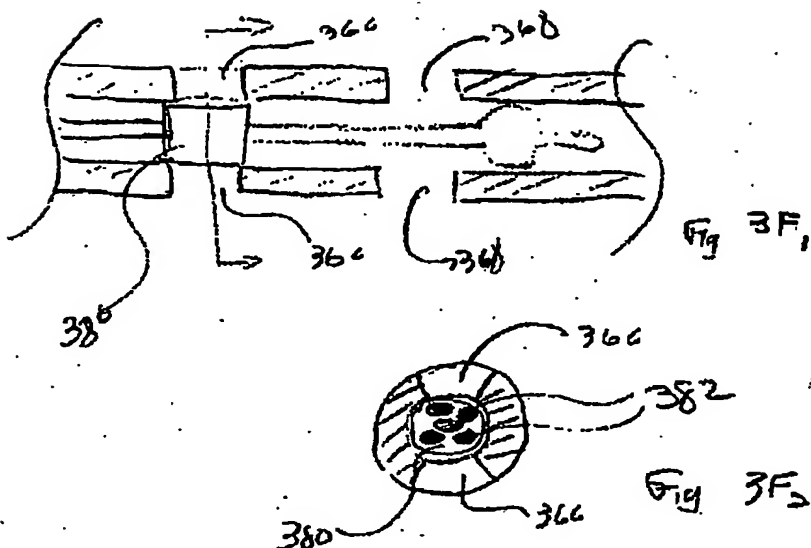
FIGURE 3C<sub>2</sub>













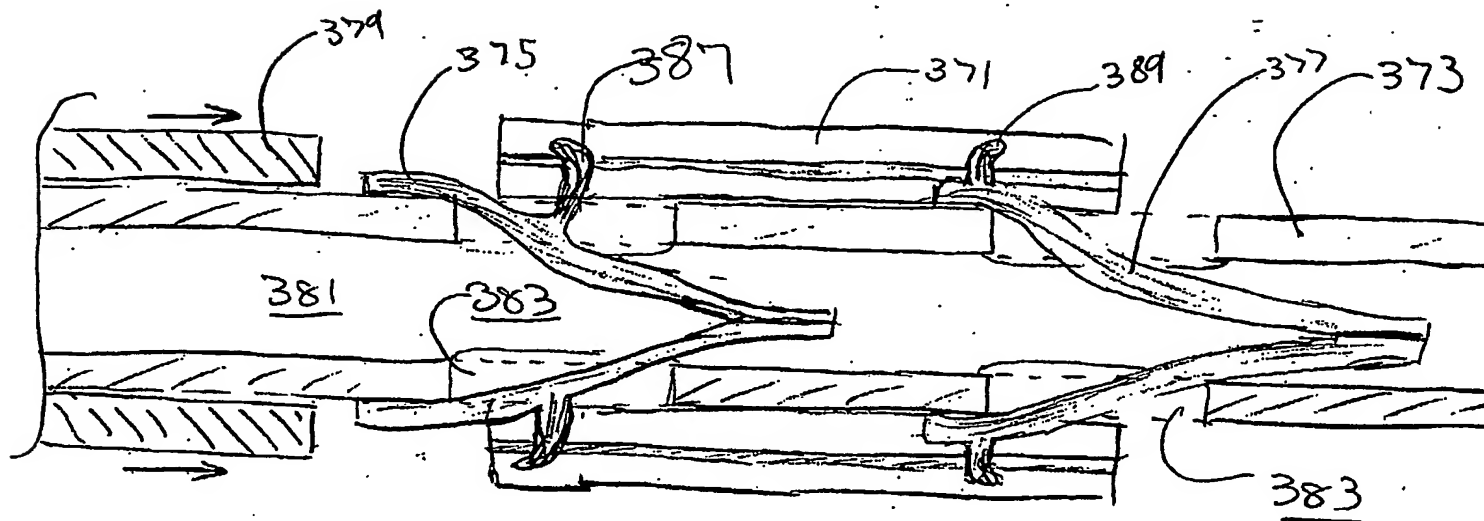


Figure 35,

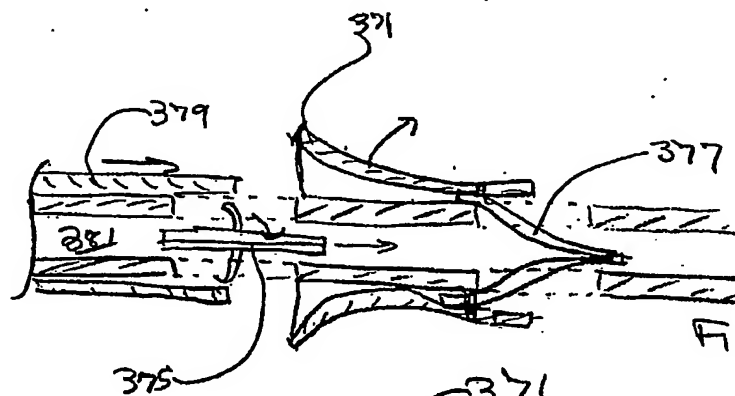


Figure 36\_2

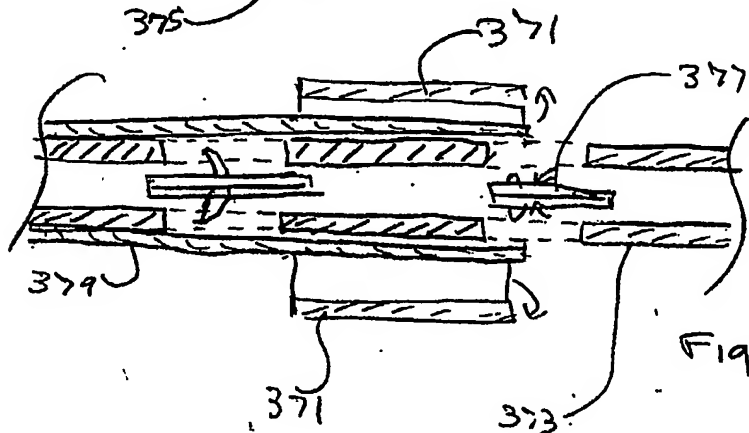
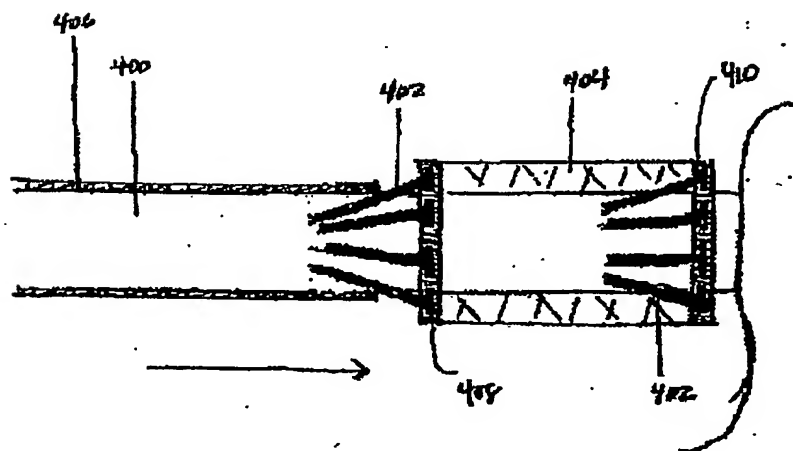


Figure 36\_3

FIGURE 4



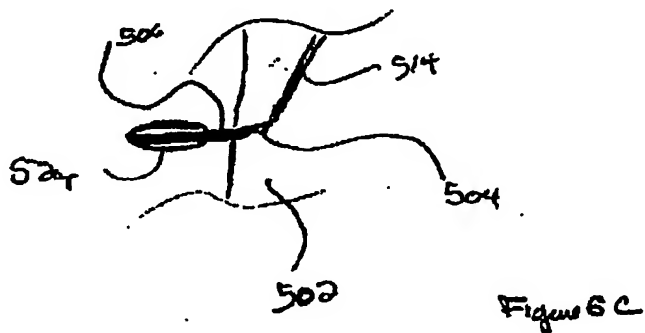
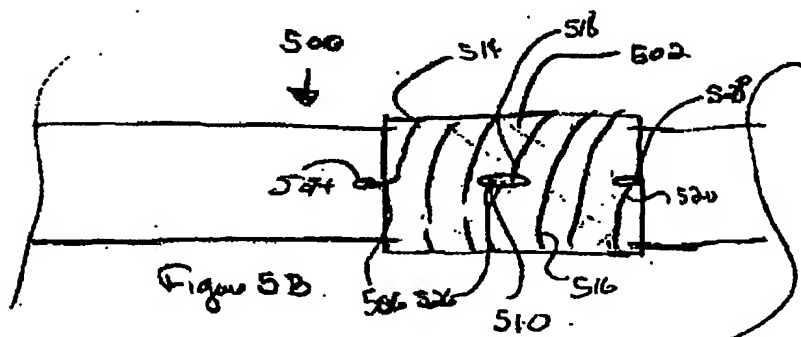
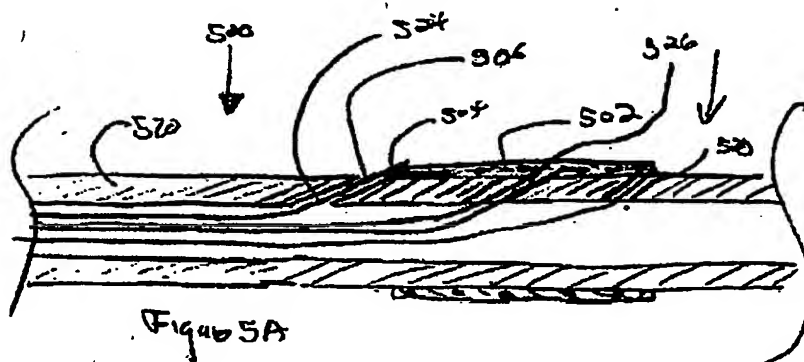


Figure 5E

FIGURE 6A

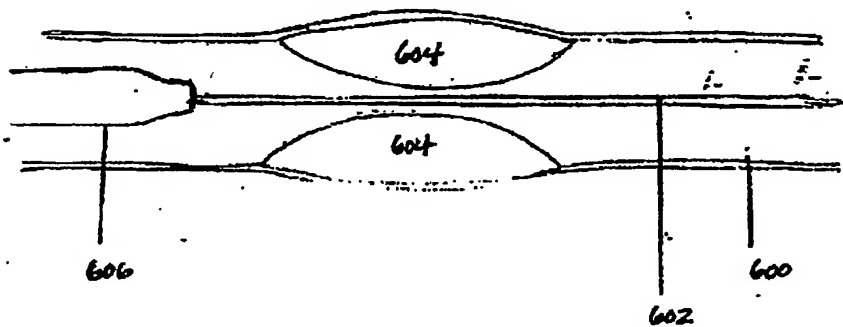


FIGURE 6B

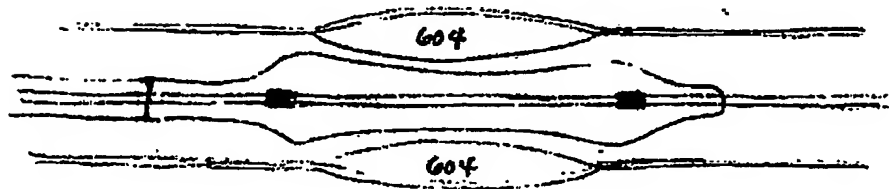


FIGURE 6C

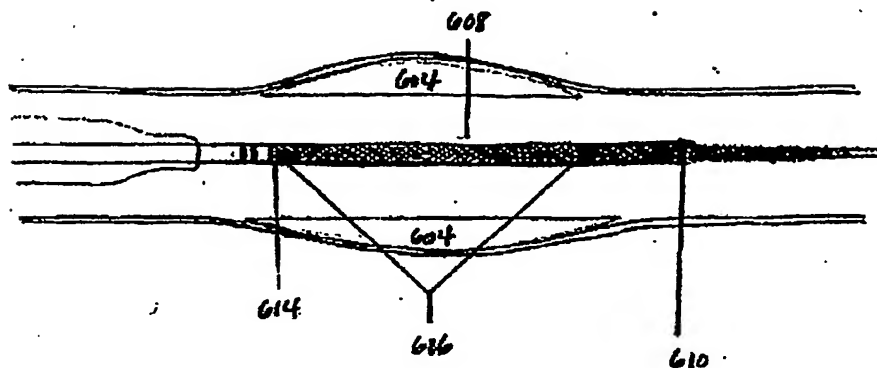


FIGURE 6D

